

ARIZONA HOUSE OF REPRESENTATIVES  
Fifty-second Legislature – First Regular Session

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CHIEF CLERK'S OFFICE

11-19-15

**COMMITTEE ON HOUSE AD HOC ON ASPECTS OF CONTACT LENS MARKET**

Report of Interim Meeting  
Tuesday, November 17, 2015  
Senate Hearing Room 2 -- 1:00 p.m.

**Convened** 1:04 p.m.

**Recessed**

**Reconvened**

**Adjourned** 3:09 p.m.

**Members Present**

Representative Heather Carter, Chairman  
Representative Randy Friese  
Representative Warren Petersen  
Michelle Ahlmer  
Dr. Daniel Briceland  
Jeff Buel  
Dr. Annette Hanian  
Michael Hunter  
Jay Magure  
Art Salas

**Members Absent**

**Agenda**

Original Agenda – Attachment 1

**Request to Speak**

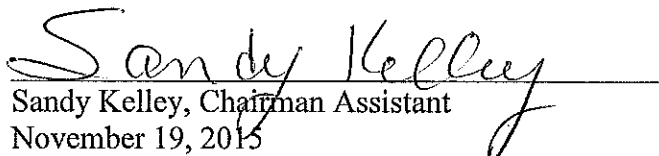
Report – Attachment 2

**Handouts given to Committee Members**

<b><u>Name</u></b>	<b><u>Handout Name</u></b>	<b><u>Attachment</u></b>
Paul Benny	Formulation of Questions and Answers	Attachment 3
Jay Magure	1-800 CONTACTS' Foreign Market Research 11-2015	Attachment 4
Jay Magure	FCLCA Enforcement Update from AOA	Attachment 5

**Presentations**

<b><u>Name</u></b>	<b><u>Organization</u></b>	<b><u>Attachments (Handouts)</u></b>
Anne Szkatulski	Opternative	Attachment 6
Steve Carlson	EyeNetra	Attachment 7

  
Sandy Kelley, Chairman Assistant  
November 19, 2015

(Original attachments on file in the Office of the Chief Clerk; video archives available at <http://www.azleg.gov>)

## CORRECTED COPY - 11/13/15

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# ARIZONA HOUSE OF REPRESENTATIVES

## INTERIM MEETING NOTICE OPEN TO THE PUBLIC

### HOUSE AD HOC ON ASPECTS OF CONTACT LENS MARKET

**Date:** Tuesday, November 17, 2015

**Time:** 1:00 P.M.

**Place:** SHR 2

### AGENDA

1. Call to Order
2. Public Testimony
3. Discussion and Review of Q&A Document Outlining Questions Raised During the Committee Hearing on 8-31-15
4. Overview of Corporate Optometry
5. Presentation on New Technologies Regarding Contact Lenses
  - Aaron Dallek, CEO/Co-Founder, Opternative
  - Anne Szkatulski, Government Affairs, Opternative
  - Dr. Steven Lee, Optometrist, Opternative
  - Steve Carlson, CEO, EyeNetra
6. Practices and Trends in International Market Places Regarding Contact Lenses
7. Discussion of Formulation of Final Report
8. Adjourn

### Members:

Representative Heather Carter, Chair  
Representative Randall Friese  
Representative Warren Petersen  
Michelle Ahlmer  
Dr. Daniel Briceland  
Jeff Buel

Dr. Annette Hanian  
Michael Hunter  
Jay Magure  
Art Salas

11/13/15  
RA

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## Information Registered on the Request to Speak System

*House House Ad Hoc on Aspects of Contact Lens Market  
(11/17/2015)*

### **2, Public Testimony**

#### **Neutral:**

Don Isaacson, AZ OPTOMETRIC ASSN



# Arizona House of Representatives House Majority Research MEMORANDUM

**Paul Benny**

Legislative Research Analyst

Committee on Banking and Financial Services

Committee on Insurance

(602) 926-4587

[pbenny@azleg.gov](mailto:pbenny@azleg.gov)

**To: Members of the House Ad Hoc on Aspects of Contact Lens Market**

**Re: Formulation of Questions and Answers**

**Date:** November 17, 2015

Members,

The following is a list of questions raised during the Contact Lens Market Committee hearing on 8-31-15. The answers were derived from the following sources: 1-800-Contacts, Johnson & Johnson, and House Research Staff. The information received and compiled is for review and discussion only and should not be interpreted as absolute.

Formulation of Answers are as follows:

- 1. Number of consumers that pay with vision insurance versus those that pay directly out of pocket?**

*Management & Business Academy-*

Vision Insurance Plans	52%
Medicare	15%
Out-of-Pocket	33%

*Johnson & Johnson-*

Vision Insurance Plans	70%
Out-of-Pocket	30%

2. **What portion of the U.S. population requires corrective vision?**

*National Eye Institute*

*Vision Council of America-*

Total % that use corrective lens	75%
----------------------------------	-----

% wear glasses	64%
----------------	-----

% wear contacts	11%
-----------------	-----

*Vision Impact Institute-*

Total % that use corrective lens	75%
----------------------------------	-----

*Of the 75%*

% wear glasses	71%
----------------	-----

% wear contacts	22%
-----------------	-----

### 3. How many types of contact lenses are there?

*Food and Drug Administration (FDA)-*

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ContactLenses/ucm062319.htm>

Soft, Rigid Gas Permeable, Extended Wear, Disposable, Orthokeratology, Decorative

*Johnson & Johnson-*

The FDA divides contact lenses into two general categories- soft and rigid gas permeable (RGP). Within those categories, lenses differ based on different combinations of materials (specific to the lens brand) and features like replacement schedule, applied wetting agent, oxygen permeability, thickness, water content, fit, and unique function- for example, orthokeratology lenses are those that alter the curvature of the wearers' cornea. With so many unique combinations, there are over 160 types of contact lenses.

*1-800-Contacts-*

Tyler's Quarterly Soft Contact Lens Parameter Guide (Vol. 32 No.3) provides information on numerous types of contact lenses.

*[Update 3]*

*Dr. Hanian-*

#### **List of Contact Lenses Allowed to be Sold in the United States**

Before medical devices, such as contact lenses are sold in the U.S., FDA reviews the marketing application from the medical device companies and determines whether the companies can release the device into the marketplace.

**Device@FDA** can help you search for detailed information about specific medical devices, including diagnostic tests. Use this web site to:

- Find out if devices have been reviewed and released for sale by FDA
- Get phone numbers and addresses of medical device companies
- Read and print patient information and instructions for use
- Learn about changes to devices since they first went on sale

Use these links to see a list of contact lenses reviewed by FDA and released for sale in the U.S.:

- Find [soft contact lenses with product code LPM](#)
- Find [soft contact lenses with product code LPL](#)
- Find [soft contact lenses with product code MVN](#)
- Find [rigid gas permeable contact lenses with product code HQD](#)
- Find [rigid gas permeable contact lenses with product code MWL](#)
- Find [rigid gas permeable contact lenses with product code NUU](#)

*November 17, 2015*

Please note that a new listing is not added until approximately five working days after the last day of the month in which the device was released into the marketplace. In some cases, it can take as long as five weeks to appear.

4. **Most commonly prescribed lens and how many have UPP attached to them?**

*1-800-Contacts-*

Johnson & Johnson, with the largest market share and with all of their products under UPP, have 10 products. Alcon has 7, Cooper has 3, and Bausch & Lomb has 1.

**[Update 1]**

*Dr. Hanian-*

Alcon (4)

Dailies Total 1, Aqua Comfort Plus Toric, Aqua Comfort Plus Multifocal, Air Optix Colors

Bausch & Lomb (1)

Ultra

Coopervision (4)

My Day, Clariti 1 Day, Clariti 1 Day Toric, Clariti 1 Day Multifocal

J&J (6)

Oasys, Oasys for Astigmatism, Oasys for Presbyopia, Trueye, 1 Day Moist, 1 Day Most for Astigmatism

**[Update 3]**

*Dr. Hanian-*

The discrepancies between 1-800's numbers and my numbers are due to pack size. 1-800 included the same brand of lens in different pack sizes; I listed the actual lens brand name.



5. **Statute reference on the expiration of a prescription?**

32-1968. Dispensing prescription-only drug; prescription orders; refills; labels; misbranding; dispensing soft contact lenses

A. A prescription-only drug shall be dispensed only under one of the following conditions:

1. By a medical practitioner in conformance with section 32-1921.
2. On a written prescription order bearing the prescribing medical practitioner's manual signature.
3. On an electronically transmitted prescription order containing the prescribing medical practitioner's electronic or digital signature that is reduced promptly to writing and filed by the pharmacist.
4. On a written prescription order generated from electronic media containing the prescribing medical practitioner's electronic or manual signature. A prescription order that contains only an electronic signature must be applied to paper that uses security features that will ensure the prescription order is not subject to any form of copying or alteration.
5. On an oral prescription order that is reduced promptly to writing and filed by the pharmacist.
6. By refilling any written, electronically transmitted or oral prescription order if a refill is authorized by the prescriber either in the original prescription order, by an electronically transmitted refill order that is documented promptly and filed by the pharmacist or by an oral refill order that is documented promptly and filed by the pharmacist.
7. On a prescription order that the prescribing medical practitioner or the prescribing medical practitioner's agent transmits by fax or electronic mail.
8. On a prescription order that the patient transmits by fax or by e-mail if the patient presents a written prescription order bearing the prescribing medical practitioner's manual signature when the prescription-only drug is picked up at the pharmacy.

B. A prescription order shall not be refilled if it is either:

1. Ordered by the prescriber not to be refilled.
2. More than one year since it was originally ordered.

G. A pharmacist may fill a prescription order for soft contact lenses only as provided in this chapter.

32-1976. Dispensing replacement soft contact lenses; prescription

A. A prescription order for replacement soft contact lenses may be dispensed under the following conditions:

1. The prescription order shall be in the form required by this chapter and shall include the name of the prescribing physician or optometrist.
2. The prescription order contains the date of issuance.
3. The prescription order for contact lenses includes the lens brand name, type, tint and all other specifications necessary to accurately dispense the prescription.

B. The prescription shall be dispensed with the exact lenses prescribed and no substitutions shall be made. The expiration date of the prescription shall be the earlier of the expiration date provided by the prescribing physician or optometrist or one year after the date of issuance. A refill of a prescription that is within sixty days of its expiration date shall be filled with no more than the sufficient quantity of replacement soft contact lenses needed through the expiration date.

***FAIRNESS TO CONTACT LENS CONSUMERS ACT***

***Public Law 108-164 108th Congress***

***15 USC 7604, SEC. 5. EXPIRATION OF CONTACT LENS PRESCRIPTIONS.***

*(a) In General.--A contact lens prescription shall expire--*

*(1) on the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription;*

*(2) not less than one year after the issue date of the prescription if such State law specifies no date or a date that is less than one year after the issue date of the prescription;*  
*or*

*(3) notwithstanding paragraphs (1) and (2), on the date specified by the prescriber, if that date is based on the medical judgment of the prescriber with respect to the ocular health of the patient.*

*(b) Special Rules for Prescriptions of Less Than 1 Year.--If a prescription expires in less than 1 year, the reasons for the judgment referred to in subsection (a)(3) shall be documented in the patient's medical record. In no circumstance shall the prescription expiration date be less than the period of time recommended by the prescriber for a reexamination of the patient that is medically necessary.*

*(c) Definition.--As used in this section, the term "issue date" means the date on which the patient receives a copy of the prescription.*

**6. Any grace period on the prescription's expiration?**

*Federal Trade Commission (FTC) Contact Lens Rule:*

<https://www.ftc.gov/tips-advice/business-center/guidance/contact-lens-rule-guide-prescribers-sellers>

**Prescription expiration**

The Rule allows prescribers to set prescription expiration dates – one year or more from the date the prescription is issued to a patient. If applicable state law requires a specific expiration period that is longer than one year, however, the prescriber must follow that law.

A prescriber may set an expiration date of earlier than one year only if that date is based on the prescriber's medical judgment about the patient's eye health. In these cases, the prescriber must document the medical reason for the shorter expiration date with enough detail to allow for review by a qualified medical professional, and maintain the records for at least three years.

7. **What happens when a person is traveling and orders contacts after the prescription's expiration?**

[Update 3]

*Dr. Hanian-*

*Information provided by this website is misleading, please refer to Dr. Hanian's information below. No lenses are legally allowed to be ordered without a valid, non-expired prescription from their eye care provider. "No prescription needed" is misleading because it doesn't mean the patient isn't required to have a valid, non-expired Rx, just that the retailer does not have to see the Rx prior to shipping. The patient verifies their Rx via an online statement saying that they have a valid, non-expired Rx from their eye care provider).*

<http://www.visiondirect.co.uk/no-prescription-needed>

**No Prescription Needed**

VisionDirect.co.uk makes it easy for you to order your contact lenses with or without a prescription. We understand that busy lifestyles can result in a misplaced contact lens prescription, that's why we trust you, if you are confident that you know your contact lens specifications, to order your contact lenses without a prescription.

**Easy ways to order your contact lenses from VisionDirect.co.uk:**

**1. Buy the contact lenses that your optician has prescribed without your prescription**

Ordering your contact lenses with no prescription through VisionDirect.co.uk is simple. Just ensure you check the details of your order against your contact lens box or the prescription given to you by your optician. Once you're confident the details are correct, proceed through checkout without asking us to verify your prescription. All orders are processed via our European company, Vision Direct BV, which is based in the Netherlands where prescriptions do not need to be checked.

Every two years it is good practice to have an eye test, to see if your prescription has changed and to detect early indications of eye conditions or even diabetes. Don't self-prescribe, and always stick to the recommendations of a professional. Any experiments with different lenses are best arranged in consultation with an optician.

If you need any help finding the prescription of your lenses please visit this page:  
Understanding your contact lens prescription

## **2. Ask us to check your prescription with your optician**

One great way of providing reassurance that your order is correct is to enter the details of your optician when you register. We'll contact them by phone and check that your order matches your prescription. We have plenty of experience in consulting opticians, and there is very rarely an issue with us making an approach.

### **[Update 1]**

*Dr. Hanian-*

This was taken directly, without editing other than adding highlighting), from [www.contactlenses.co.uk](http://www.contactlenses.co.uk) (the UK equivalent to our 1-800 Contacts or other online retailers).

Legislators are being misled when they are told that you don't need a prescription to order contacts in Europe. The rule is that on-line retailers don't need to see the Rx or have it downloaded, but you do need to have annual exams and a contact lens fitting in order to get contacts and the consumer must sign a waiver stating the RX is current. The contact lens DOES specify brand/ manufacturer in the UK.

### **Prescriptions & Eye Tests**

#### **What is a Contact Lens Prescription?**

A contact lens prescription will provide details of the brand, lens parameters and the power. It will be signed and dated by your practitioner. A contact lens prescription is different from a sight test prescription. Contact lenses come into direct contact with the eye and, for this reason, there are additional measurements needed for fitting a contact lens and these need to be included in the prescription.

We do not require **to see** your contact lens prescription when you order contact lenses. When you order from us, you will need to agree to our Terms & Conditions which indicates acceptance that your prescription is current and suitable for you. It is important to have an annual contact lens checkup with your eye care practitioner to ensure that your eyes stay healthy.

If you are new to contact lenses you will need to visit your Optician or ye Doctor to have a `contact lens fitting`. They will measure your eyes, chat to you about the different type of contact lenses available and what would best suit your requirements and then try some lenses in your eyes. Once they are satisfied with how they fit and adjusts for the best vision, they can issue a contact lens prescription that you can then use to order online.

## Contact Lenses without Prescription

We are often asked if you can order your contact lenses online without a prescription? After all, it is common to lose your prescription, or for it to be just out of date, and you are desperate for contact lenses. Sometimes, a customer is just uncomfortable asking his optometrist for the prescription so that they can buy online, or they don't want them to know that you are buying online. The answer is YES.

Even under USA law it is not illegal for a US customer to order contact lenses from a Non - USA site. (This is misleading because it doesn't say that it is illegal to sell without a valid Rx in US). We despatch to you from the UK, so you are quite safe, and we only use guaranteed manufacture brand lenses.

## Commonly Asked Questions

*Is it safe to order Contact lenses without a Prescription?*

**It is safe** to order replacement lenses from a trusted supplier if:

- you are wearing the lenses and have no current problems i.e red eyes/blurred vision/discomfort.
- you have been correctly fitted with contact lenses originally by a qualified practitioner.
- you have a contact lens check up once a year.

**It is not advisable** to:

- order contact lenses online if you have never been fitted for them before. First get fitted, get comfortable with the lenses and then, when you are happy, you can look to save money by ordering online for your replacement contacts.

This is taken directly from [www.perfectlens.ca](http://www.perfectlens.ca), the Canadian equivalent of our online retailers, without correcting spelling and grammar or other editing other than highlighting.

Q01. Do I need a prescription to place an order?

- ❖ Yes, you must have a valid prescription under the applicable provincial territorial laws. Please ensure that your order is exactly the same as the prescription that was given by your eye care provider and that three lenses fit your eye comfortably. We do not take responsibility for any medical problems which might occur.

- ❖ Q01. Do I need to have my eyes examined before purchasing contact lenses?

- ❖ Yes, contact lenses are medical devices and your eyes must be examined by a certified lens care professional before purchasing our merchandise. Additionally, you need to follow the manufacturer's instructions and any guidance/instructions given to you by your eye care professional.

## **Glasses and Contact Lenses in British Columbia: New law makes buying contacts online easier**

In 2010 significant changes were made to B.C. regulations regarding the sale of prescription spectacles and contact lenses. These changes remain highly controversial, with the Canadian Association of Optometrists opposing the changes on health and safety grounds.

Here are some of the frequently asked questions about the changes, and what they mean to you (this applies to residents of B.C. only):

### **Can I buy contacts or glasses online without a prescription?**

Residents of B.C. are no longer required to show their prescription when ordering contacts online. However, you should still have a recent prescription, and it's recommended that you receive periodic full eye exams by an optometrist, which will screen for serious eye disease.

### **Is my prescription from another province valid in B.C.?**

Yes, now eye prescriptions from Ontario, Quebec, Alberta, and other provinces and territories can be filled in B.C. without a re-examination.

**8. List of medical devices in Class 1; Class 2; Class 3.**

*FDA list of Ophthalmic Devices:*

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=886>

**Class I General Controls**

- Require a minimum level of FDA regulation to provide a reasonable assurance of safety and effectiveness
- Examples: tongue depressors, arm slings, hand-held surgical instruments, examination gloves, elastic bandages, and toothbrushes

**Class II General Controls and Special Controls**

- Require additional regulation to provide reasonable assurance of safety and effectiveness, such as labeling and post market surveillance
- Examples: infusion pumps, hearing aids, X-ray systems, and powered wheelchairs

**[Update 3]**

*Dr. Hanian-*

Add to Class II examples – Single Use Contact Lenses

**Class III General Controls and Premarket Approval**

- Pose a higher risk of injury or illness
- Subject to premarket approval and increased regulation aimed at ensuring their safety and effectiveness
- Examples: heart valves, pace makers, dental laser, intraocular lenses

**[Update 3]**

*Dr. Hanian-*

Add to Class III examples – Multiday Use and Extended Wear Contact Lenses



## 9. How many prescriptions are filled in office vs online retailer?

FTC Study 2005-

<https://www.ftc.gov/sites/default/files/documents/reports/strength-competition-sale-rx-contact-lenses-ftc-study/050214contactlensrpt.pdf>

### Largest Eyecare Retailers 2003

Retailer-	Sales (\$mil)
Luxottica Group (LensCrafters, Pearle Vision, Sears, Target, BJ's).....	\$2,508
Wal-Mart .....	\$968
Eye Care Centers of America (EyeMasters, Visionworks, Vision World, Hour Eyes, Dr. Bizer's Vision World, Dr. Bizer's Value Vision, Doctor's ValuVision, Doctor's Visionworks, Stein Optical, Eye DrX, Binyon's) .....	\$370
Costco Wholesale .....	\$269
National Vision (The Vision Center (operated in Wal-Mart), The Optical Shoppe (in Fred Meyer), National Vision Optical) .....	\$242
U.S. Vision (J.C. Penney Optical) .....	\$150
Consolidated Vision Group (America's Best, America's Contacts And Eyeglasses).....	\$126
D.O.C. Optics (D.O.C. Eyeworks, D.O.C. Optique, SportVision, SEE, City Eyes) .....	\$97
Emerging Vision (Sterling Optical, Site for Sore Eyes, Singer Specs).....	\$92
10 Empire Vision Centers (Empire Vision Centers, Davis Vision Centers, Total Vision Care).....	\$86

### Patient Visits By Channel

Channel	Share of Patient Visits	Estimated Share of Filled
Prescriptions Independent M.D.	14.1%	12.3%
Independent O.D.	52.6%	45.8%
Independent Stores and OD Groups	12.2%	10.6%
Chain Retailers and Optical Stores	21.0%	18.4%
Mail Order/Internet	N/A	13.0%

### Share of Sales By Channel

Channel	Share of Sales
---------	----------------

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Independent M.D. ....	4.3%
Independent O.D. ....	64.3%
Mass Merchandisers.....	13.9%
Retail Chains.....	9.5%
Mail Order/Internet.....	8.0%

*Johnson & Johnson-*

Industry sales data indicates that approx. 85% of prescriptions are filled in the office where the doctor is located (e.g. an independent Optometrist or Ophthalmologist) or in a retail setting (e.g. Wal-Mart), and approx., 15% are filled online.

*1-800- Contacts-*

Internet	17%
Retailers	28%
Eye Care Professionals	55%

**[Update 1]**

*Dr. Hanian-*

MMWR Vol. 64 No. 32 / 2015

Internet	20%
Retailers	10%
Officer Provider	70%

**[Update 3]**

*Dr. Hanian-*

Added for Clarification

MMWR Vol. 64 No. 32 / 2015

Internet	20%	Actual 20.8; average 23.0%
Retailers	10%	Actual 10.4; average 9.2%
Officer Provider	70%	Actual 66.9; average 66.3%

Actual numbers from MMWR depend on type of lens. Online Retailers sell Daily, Planned Replacement and Overnight

**TABLE 2. Prevalence of risk behaviors for eye infections\* among contact lens wearers, stratified by type of contact lens — United States, 2014**

Risk factor/Behavior or	% of wearers, by type of contact lens				
	Daily disposable (n = 154)	Planned replacement, soft (n = 730)	Overnight, soft† (n = 182)	Rigid (n = 85)	Overall (n = 1,141)

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**Where lenses were purchased**

Provider office	(66.9)	(64.7)	(67.5)	(84.0)	(66.9)
Retail store	(8.4)	(11.8)	(7.5)	(8.6)	(10.4)
without eye exam					
Internet	(23.4)	(21.3)	(24.4)	(4.9)	(20.8)
Had a red/painful eye while wearing contact lens that required a doctor's visit (ever)	(29.2)	(29.3)	(35.3)	(28.9)	(30.2)

70%

**[Update2]**

Mr.Salas-

VM Top 50 U.S. Optical Retailers 2014

<u>Rank</u>	<u>Retailer</u>	<u>2013 Sales (\$ Millions)</u>
1	Luxottica Retail	2,336.0
2	Vision Source	1,969.0
3	Wal-Mart Stores	1,476.0
4	Visionworks of America	784.8
5	National Vision	780.0
6	Costco Wholesale	757.0
7	Refac Optical Group	236.9
8	Eyemart Express	220.0
9	For Eyes/Insight Optical	165.0
10	Cohen's Fashion Optical	150.4

**[Update3]**

Staff- The information regarding retailer sales may not be appropriate with regards to the underlining question. The information received from 1800-Contacts, Johnson & Johnson, and Dr. Hanian answers this question appropriately.

**[Update 3]**

Dr. Hanian-

Clarification that the above sales include eye exams, eyeglass frames, eyeglasses lenses and coatings, sunglasses and contacts. This is not a list of the largest contact lens retailers.

10. **How many emergency room visits are related to vision?**

Health Cost and Utilization Project-2008

<http://www.hcup-us.ahrq.gov/reports/statbriefs/sb112.pdf>

Findings Overall population

In 2008, there were 636,619 Emergency Department (ED) visits related to eye injuries. This represents a rate of 209 ED visits per 100,000 population. On average, every day there were 1,744 ED visits related to eye injuries. About 3.1 percent of patients seen in the ED for eye injuries were admitted to the hospital— compared to 8.1 percent of ED visits for all other types of injuries.

*Johnson & Johnson-*

Every year, nearly one million Americans make doctor's visits seeking treatment for contact lens disorders. In 2013, contact lens patients made an estimated 930,000 eye-related visits to doctor's offices and outpatient clinics, and another 58,000 to emergency rooms. Wearing contact lenses is the largest single risk factor for developing an eye infection, specifically keratitis, which is an infection of the cornea that causes pain and inflammation and can lead to blindness in severe cases.

Keratitis can stem from a number of ill-advised, contact lens-related behaviors, including wearing lenses for longer than the prescribed modality or wearing lenses that were not specifically approved by an ECP for the patient's ocular health needs.

(Source: CDC)

**[Update1]**

*Dr. Hanian-*

CDCNewsroom HomePress MaterialsCDC Newsroom Releases

CDC analyzed national databases of outpatient care centers and emergency rooms to develop the first national estimates of how much keratitis occurs in the United States. CDC experts found that Americans made an estimated 930,000 visits to doctor's offices and outpatient clinics and 58,000 emergency room visits annually due to eye infections. Women were slightly more likely to be affected than men, accounting for 63 percent of office visits and about 55 percent of emergency room visits. The condition was spread relatively evenly across age groups. The report was published November 13 in CDC's Morbidity and Mortality Weekly Report.

- Additional Information provided is a list of states' contact lens prescription expiration periods:

### **Florida**

463.012 Prescriptions; filing; release; duplication.—

(1) A licensed practitioner shall keep on file for a period of at least 2 years any prescription she or he writes.

(2)(a) A licensed practitioner shall make available to the patient or her or his agent any spectacle prescription or duplicate copy determined for that patient. Such prescription shall be considered a valid prescription to be filled for a period of 5 years.

(b) A licensed practitioner shall make available to the patient or her or his agent any daily wear soft contact lens prescription or duplicate copy determined for that patient. **Such prescription shall be considered a valid prescription to be filled for a period of 2 years.**

### **California**

2541.2. (a) (1) The expiration date of a contact lens prescription **shall not be less than one to two years** from the date of issuance, unless the patient's history or current circumstances establish a reasonable probability of changes in the patient's vision of sufficient magnitude to necessitate reexamination earlier than one year, or the presence or probability of visual abnormalities related to ocular or systemic disease indicate the need for reexamination of the patient earlier than one year. If the expiration date of a prescription is less than one year, the health-related reasons for the limitation shall be documented in the patient's medical record. In no circumstances shall the prescription expiration date be less than the period of time recommended by the prescriber for reexamination of the patient.

### **Nevada**

NRS 637.175 Expiration of prescriptions. A prescription received by a dispensing optician shall be deemed to have an **expiration date of 2 years** after the date the prescription was issued unless the practitioner who wrote the prescription includes on the prescription a different period.

### **Texas**

Prescriptions are valid **for at least one year** after the correct prescription has been determined, unless a shorter term is warranted by the health of the patient's eyes or by potential harm to the health of the patient's eyes

### **Minnesota**

Subd. 2. *Prescription expiration date.* -- A prescription written by an optometrist or physician must **expire two years after it is written**, unless a different expiration date is warranted by the patient's ocular health. If the prescription is valid for less than two years, the optometrist or physician must note the medical reason for

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the prescription's expiration date in the patient's record and must orally explain to the patient at the time of the eye examination the reason for the prescription's expiration date.

# 1-800 CONTACTS' Foreign Market Research 11-2015

Country:	Denmark	Finland	Germany	Norway	Sweden	United Kingdom	Netherlands	France	Japan	British Columbia (Canada)
Prescription required to purchase contact lenses?	NO	YES	NO	NO	NO	YES	NO	NO	NO	NO
Prescriber required to release prescription to patient?	NO: No prescription required to purchase	NO	NO: No prescription required to purchase	NO: No prescription required to purchase	YES	YES	NO: No prescription required to purchase	NO: No prescription required to purchase	NO: No prescription required to purchase	YES
If given, what does a prescription typically include? (Brand, Power, Diameter, etc...)	Not required, but when it's given it typically includes: power, base curve, diameter, material & modality. Brand is not required and would be "scarcely relevant."	The model prescription of the "Ethical Council of Optometry" includes: spherical correction, cylindrical correction, axis, additionally refractive power, base curve, diameter and lens information (which may include brand and or materials).	Not required, but when it's given it typically includes: sphere, cylinder, axis and pupil distance. Brand is generally not given.	Norwegian Association on Optometry recommends providing patients with a "bill" which contains all of the needed information about fitted contact lenses.	Not required, but when it's given it typically includes: brand, model of the contact lens and power.	There is no law requiring brand, but the specification usually indicates a brand. It also lists a power, base curve, peripheral curves, diameter, material and modality.	No specific requirements but an online seller in the Netherlands lists power, base curve, diameter, cylinder and axis as being included, along with an add power.	No information obtained	Not required, but when it's given the contact lens instruction sheet includes product name & manufacturer, base curve, sphere, diameter, cylinder, axis, quantity of boxes, method of use, issue date, expiration date and doctor's eye care provider.	No information obtained
Must a given prescription include an expiration date?	re	NO	NO	NO	NO	YES	NO	No information obtained	NO	No information obtained
Firm / Attorney providing research and date of research:	Aumento Advokatsfirma; Paul Neale; March 13, 2015	Krogerus; Sino Autio & Tom Fagerman; March 13, 2015	GSD Gilling Kramer Döring Stagatz; Andreas Witt & David Budd; March 20, 2015 & November 6, 2015	SGB Storholken; Knut Anders Gronland; March 11, 2015	Everheds; Richard Jacobsson & Emelie Svensson; March 12, 2015	Reynolds Porter Chamberlain LLP (RPC); Oliver Bray; April 7, 2015	Bavelaar & Bavelaar; Pieter Ardens Koppers; April 24, 2015	<a href="http://www.europe-consummateurs.eu/en/co-rsumer-topics/buying-of-goods-and-services/shopping-in-france/purchase-of-glasses-and-lenses/">http://www.europe-consummateurs.eu/en/co-rsumer-topics/buying-of-goods-and-services/shopping-in-france/purchase-of-glasses-and-lenses/</a> ; <a href="http://www.lexology.com/library/detail.aspx?l=4256f052-aae8-421d-8e22-4f7b96608c0d">http://www.lexology.com/library/detail.aspx?l=4256f052-aae8-421d-8e22-4f7b96608c0d</a>	Mori Hamada & Matsumoto; Takeyuki Kikita; August 26, 2015	Internal research

## 1-800 CONTACTS' Foreign Market Research 11-2015: Germany

We've asked a law firm in Germany, GKD, to conduct extensive research for 1-800 CONTACTS in relationship to the reasoning behind the lack of regulation of contact lenses within Germany. The reoccurring theme that came from their research was simple: contact lenses as a medical device are perceived to be safe and have lead to very few medical issues within Germany.

Germany is not a small market:

1. In 2014 Germany consumed nearly 1,530,000 million Euros worth of contact lenses, which was the highest out of any EU country in 2014. (1,640,000 million in US Dollars)
2. Germany's contact lens consumption in 2014 was 23% of the EU market. The UK was second with 21%

Regulation of contact lenses in Germany has been proposed, but hasn't been embraced in large part because of a lack of medical evidence for the need of additional regulation:

1. In 2014 the Zentralverband der Augenoptiker (ZVA = German Central Association of Opticians) lobbied for additional regulation on contact lens sales and distribution. The Federal Ministry of Health in Germany didn't follow the ZVA's recommendations and chose to not add additional regulation to the new Medical Devices Supply Regulation of 2014. After reviewing the Federal Ministry of Health's decision in 2014 the ZVA identified 2 main reasons for their decision:
  1. There was a decision by the European Court of Justice (ECJ Case c-108/09) regarding contact lens sales via the internet where it was ruled by the ECJ that customers can be advised, in the same way, before the supply of contact lenses, as part of the process of selling lenses via the internet by means of interactive features on the website as they would if they were to visit an eye care provider. The ECJ also specified that online distributors could make a qualified optician available to a customer for the purpose of giving the customer individualized information, at a distance, regarding the proper use and care of contact lenses.
  2. The Federal Ministry of Health requires the proof of concrete examples of health effects. There are no or nearly no reported health problems in Germany regarding contact lenses. If there are reports they generally occur because of insufficient patient care of their contact lenses, but the devices in and of themselves are not dangerous.
2. The Federal Institute for Drugs and Medical Devices (BfArM) reported the same reasoning for a lack of regulation on contact lenses. They attribute the lack of regulation directly to the lack of a proven medical need for regulation.





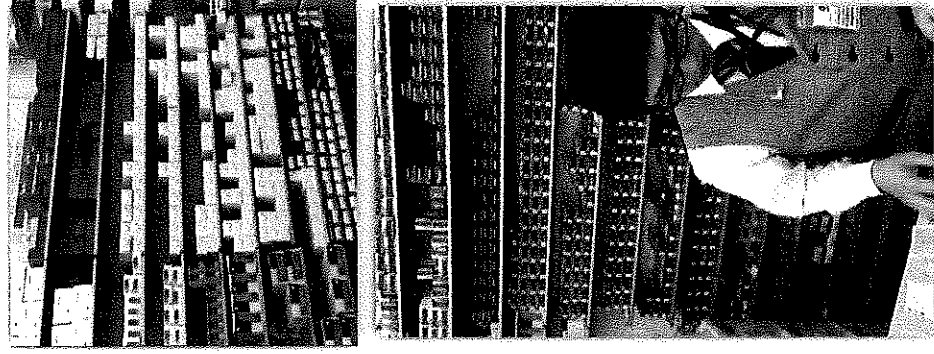
## 1-800 CONTACTS' Foreign Market Research 11-2015: Sweden & Japan

Contact lenses can also be purchased over the counter in other markets, like Sweden and Japan. Germany is not alone. We were able to find contact lenses that could be purchased, over the counter without a prescription in both Sweden and Japan:

### Sweden:



### Japan:







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## FCLCA Enforcement Update from AOA

### Advisory From The AOA General Counsel

**SUBJ:** FCLCA Enforcement Update

**FROM:** Mike Stokes, AOA General Counsel

**TO:** AOA Affiliate Presidents and Executive Directors

Interim Response to State Association Inquiries Concerning 1-800 CONTACTS, Inc.'s Shifting Tactics on Contact Lens Prescription Verification Requests to Doctors

The AOA continues to express grave concerns to the Federal Trade Commission about the sales tactics of online retailers of contact lenses. The FTC enforces the Fairness to Contact Lens Consumers Act (FCLCA) and AOA has met with Commission staff twice in the past 8 months and provided written documentation about the actions of online contact lens retailers.

Recently, the AOA has received increasing numbers of complaints from doctors regarding forms used by 1-800-CONTACTS. These forms claim to be acting on the patient's behalf and demand the patient's contact lens prescription rather than rely on the traditional prescription verification forms that are sent to doctors after a patient orders contact lenses. Instead, the retailer demands a doctor provide a patient's complete prescription. On the forms, 1-800-CONTACTS claims the retailer has received the patient's authorization to contact the doctor to obtain a complete copy of the patient's contact lens prescription. The use of such forms is actually not new—they were seen at least a decade ago. After a long hiatus, 1-800-CONTACTS seems to have reintroduced the form and appears to have greatly expanded their use in recent weeks. Many doctors and their staff members are unfamiliar with the forms and have questions regarding the legitimacy of the requests, the doctor's obligations under the FCLCA to respond to such requests, and whether the HIPAA Privacy Rule requires them to obtain patient consent prior to releasing a prescription.

Many doctors who have received these forms have noted that the prescription referenced on the form is outdated or otherwise incorrect. Several doctors have reported to AOA that upon receiving the request from the retailer, the doctor has reached out to the patient to inform him/her that the request for the prescription had been received, but that incorrect information was noted on the form. Some doctors have reported to AOA that when they have discussed these requests with patients, the patient has indicated the patient did not intend to authorize the retailer to contact the doctor for this information.

Upon investigating this issue, the AOA found that the retailer seeks patient authorization through the use of a pre-checked box in small print at the end on the contact lens online order form. The box automatically defaults to being checked, is included on the final line on the contact lens order form and indicates, "Contact my eye care professional to obtain a copy of my written prescription to validate existing and future orders." AOA has reported to FTC officials that these forms put doctors in



## Reporting Issues to FTC

This guidance is based on the FTC's 2006 letter to the AOA on this issue. The AOA continues to believe that the FTC's interpretation of the FCLCA with regard to prescription requests is flawed, **but until such time as the FTC modifies its position, the AOA recommends following the 2006 guidance.**

The AOA will continue to advocate for a change in the FTC's guidance so that the application of the FCLCA is logical and consistent with the plain language of the statute and the FTC's own comments at the time the final rule was adopted. Furthermore, the AOA continues to express concerns about the negative impact on patient health and safety when medical devices such as prescription contact lenses are distributed unchecked. The AOA will continue to gather information from members about any improper retailer actions based on invalid or inaccurate prescriptions.

The AOA continues to receive many reports from doctors regarding practices of online contact lens retailers that put patients' eye health at risk. Doctor reports of these incidents are critical to AOA's ability to advocate for policies that better protect patients. Please report any issues with online contact lens retailers to Kara Webb at [kcwebb@aoa.org](mailto:kcwebb@aoa.org). Incidents should also be reported directly to the Federal Trade Commission (FTC), oversees enforcement of the Fairness to Contact Lens Consumers Act (FCLCA). The FTC's online complaint system can be accessed at: [ftccomplaintassistant.gov](http://ftccomplaintassistant.gov)

1. Remarks of David Vladeck, Director FTC Bureau of Consumer Protection, before the National Advertising Division Annual Conference, New York, NY (October 5, 2009).

## NO ACTION REQUIRED

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Tel: 518.449.7300  
Fax: 518.432.5902

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Website Development and VSite: Content Management by ES11

Remarks Prepared by **Opternative** for the

**Arizona House of Representatives**  
**Ad Hoc Committee on Aspects of Contact Lens Market**  
November 17, 2015 — 1:00pm — SHR 2

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My name is Aaron Dallek, and I am the CEO and Co-Founder of **Opternative**. I am joined by Dr. Steven Lee, OD, our Chief Science Officer and Co-Founder, and Anne Szkatulski, our Director of Government Affairs.

Opternative is a telehealth provider of online refractive exams, allowing patients across the country to get a physician-issued prescription for contacts online. Our innovative technology is safe, convenient, and affordable.

According to VisionWatch (which is a consumer measurement tool for the eyewear industry), **67 million Americans have not had an eye exam in the last 2 years because of cost or convenience**. At Opternative, we are addressing this problem head-on by creating a scientifically accurate alternative for a patient to obtain a prescription for contacts, while encouraging patients to think about their eye health and see their eye doctor in person regularly.

**Opternative is on the forefront of telemedicine by giving patients control of when and where they get a refractive exam.** With our clinically proven technology, consumers age 18 to 40 can get a physician-issued prescription for contacts from the comfort of home, whenever it is convenient for them, and for a fraction of the price of an in-office refraction. The consumer then has the power to take their prescription to any retailer of their choosing.

**Our exam works by utilizing the tools that pretty much any patient would otherwise have at their disposal: a computer and a smartphone.** To get started, a patient would come to our website, sign up and create an account with us, and answer a few preliminary questions: their smartphone number and their shoe size.

We ask for the patient's smartphone number so that we can sync up their phone to act as a remote control for their computer -- but more on that later.

We ask for the patient's shoe size to assist them in moving 10 feet away from their computer, by telling them to take the appropriate number of heel-to-toe steps based on their shoe size.

The patient then answers a series of medical history questions, such as whether they have a history of glaucoma or diabetes, whether they experience migraines, etc. These questions serve two purposes: (1) they help us filter out patients who are better suited for an in-office exam, and (2) for those patients for whom an online refraction is appropriate, they help us create a more complete medical record.

One particular scenario I would like to point out is that if someone comes to the Opternative exam and tells us that **this is their first prescription for contacts, we refer them to see an in-person eye care provider.**

We do not prescribe contact lenses to a patient who has never had a contact lens fitting. We believe a patient should always have their first contact lens experience with an in-person provider who can teach them proper fitting and hygiene.

We do, however, provide refractions and, where appropriate, prescriptions for individuals who have experience successfully wearing contact lenses.

Once the patient has answered the medical history questions and shared any other relevant information with us, we send them a text message to their smartphone that contains a customized link. By clicking the link in their text message, Opternative turns their smartphone into a remote control for their computer's browser.

We then guide them to take the appropriate amount of steps away from their computer to reach 10 feet, and they begin the exam.

The exam experience takes about 25 minutes, at which point Opternative gathers up all the patient data, medical history, and relevant consents, and forwards the information **to a doctor licensed in the patient's state via our HIPAA-compliant portal.**

The doctor reviews the information and determines the best course of action for the patient -- whether a prescription, a request for more information, or advising the patient to see an eye doctor in person.

If the doctor determines that the patient should be issued a prescription, the prescription is made available to the patient within 24 hours through our HIPAA-compliant portal, and the patient can take that prescription to any retailer of their choosing.

Throughout the exam, we regularly encourage our patients to visit an eye care professional every 2 years to receive an eye health exam, per the American Optometric Association guidelines. Additionally, because the American Academy of Ophthalmology recommends that healthy adults receive an eye health exam every 5 years, we limit the amount of times a patient can take the Opternative exam within a span of 5 years without proof of an in-person eye health exam. Our patients' health is critical to us, and we take care to encourage them to address their overall eye health.

**Opternative's mission is to "help the world see and feel better."** Our technology will increase access to and awareness of broader eye health, and provide consumers with a safe, convenient, and less expensive eye prescription alternative.

Here is a link to a video that will walk you through our exam experience:  
[vimeo.com/134751487](https://vimeo.com/134751487)

Thank you very much for the opportunity to be here today, and I'm happy to answer any questions you may have.

**Aaron Dallek, CEO and Co-Founder**  
Opternative  
[aaron@opternative.com](mailto:aaron@opternative.com)

**Dr. Steven Lee, OD, CSO and Co-Founder**  
[steven@opternative.com](mailto:steven@opternative.com)

**Anne Szkatulski, JD, Dir. of Government Affairs**  
[anne@opternative.com](mailto:anne@opternative.com)



**EyeNetra**

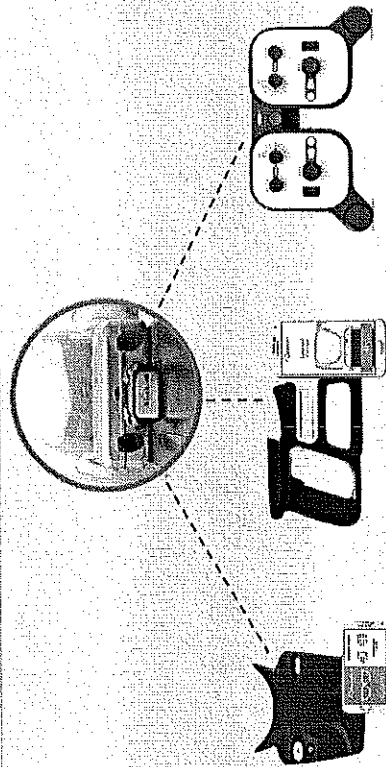
Steve Carlson  
CEO

Smartphone-Powered Refraction

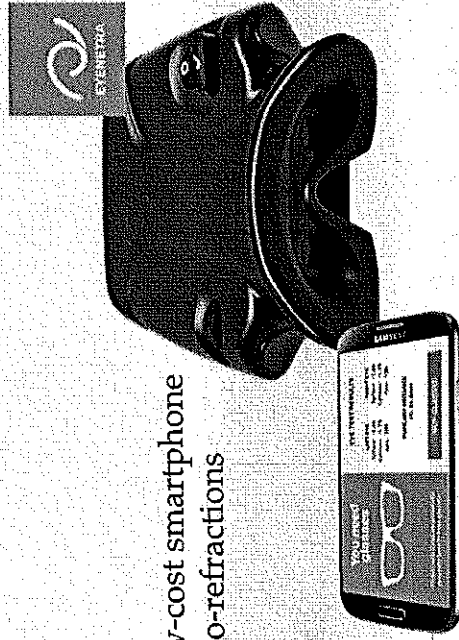
"Honey, we shrunk the eye doctors office"

Forward looking statements, written or oral, of any kind  
cannot be guaranteed by the company

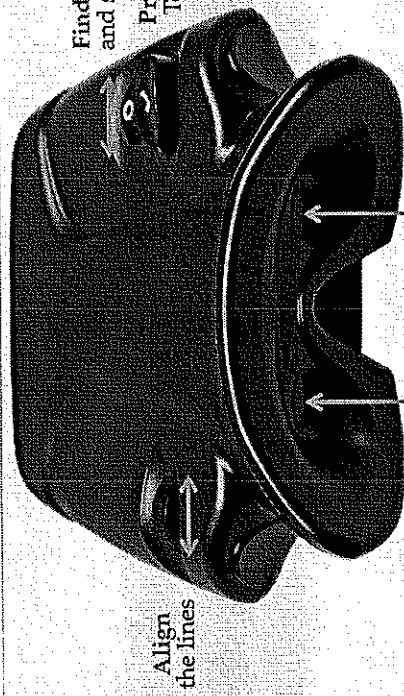
## Complete Refractive Testing System



Portable low-cost smartphone  
for auto-refractions

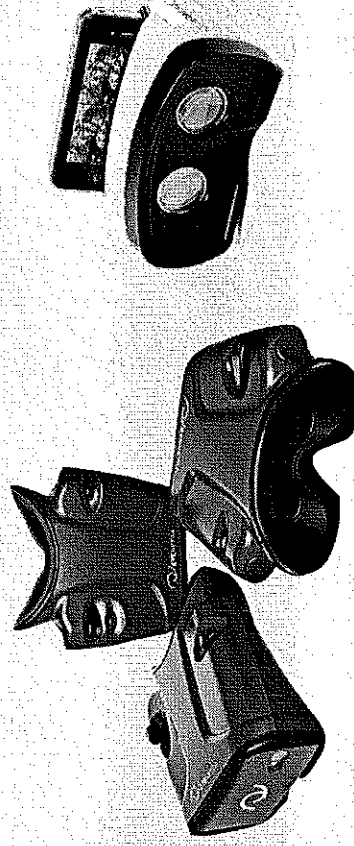


## Look Inside, Find, Align and Confirm

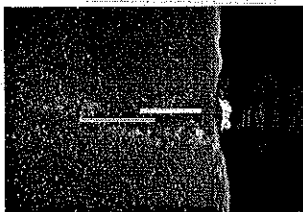
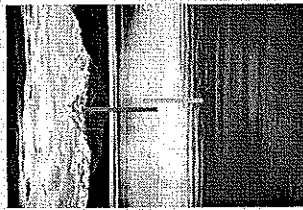
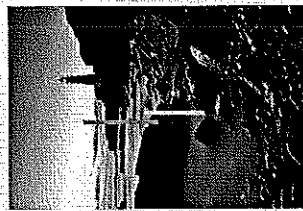


Find the brightest  
and sharpest lines  
Press button  
To confirm

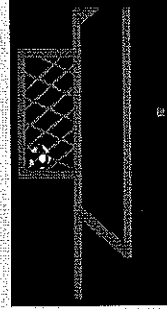
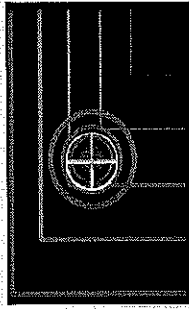
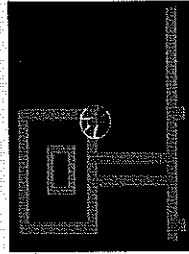
## It can also be a Binocular VR Display



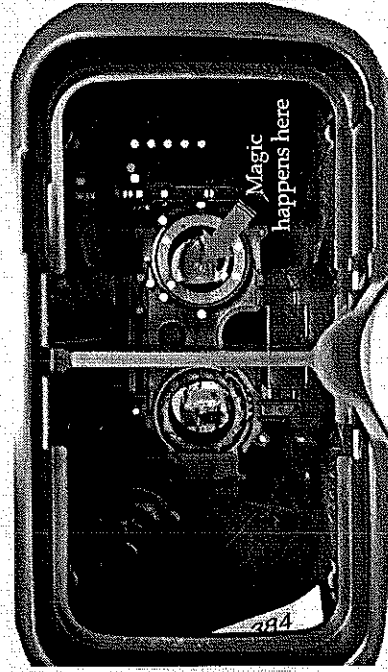
## Choose Your Accommodation Relaxation Stimulus



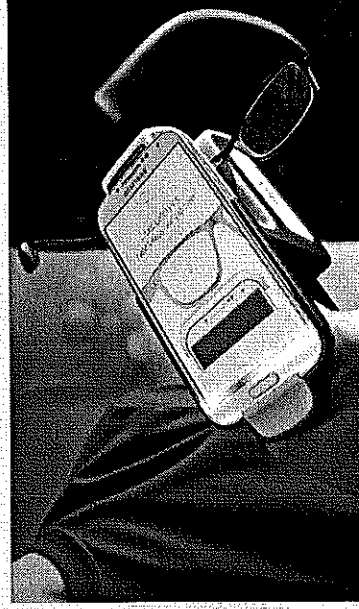
## Choose Your Game



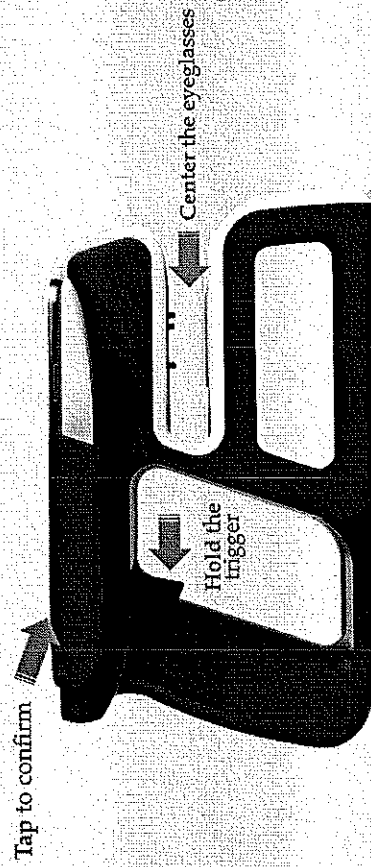
## What's Inside



## Introducing A New Handheld Lensometer

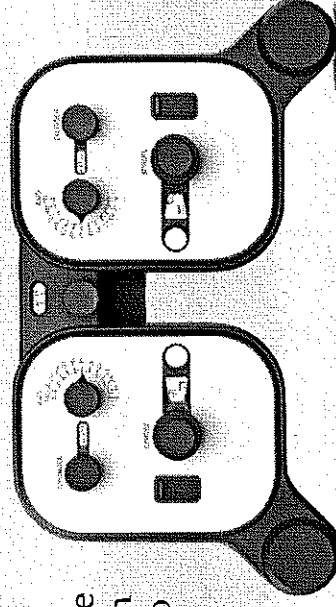


## Compact, Accurate and Easy to Use

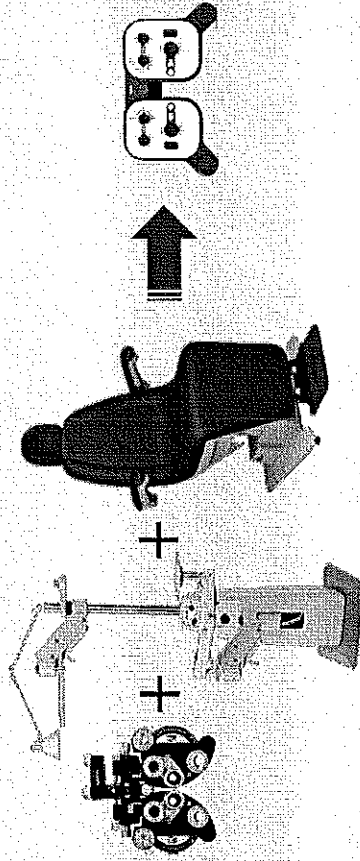


## Neuropter

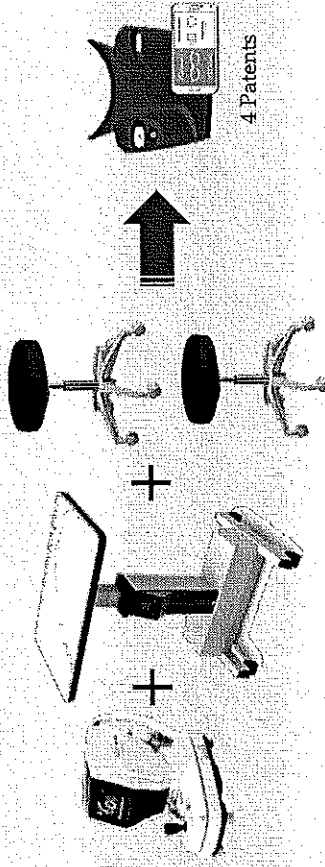
Subjective  
Refraction  
on the go



Reduce space, lower cost, add portability

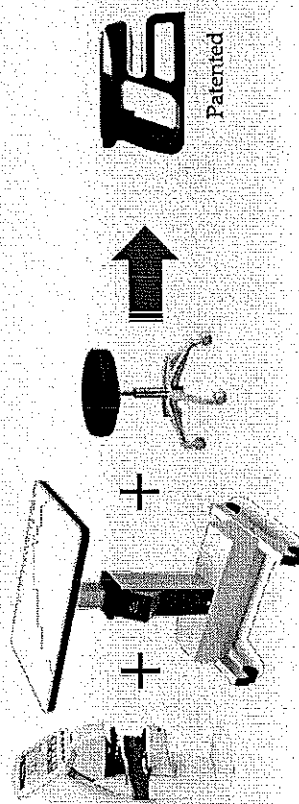


Reduce space, lower cost, add portability








4 Patents

Reduce space, lower cost, add portability

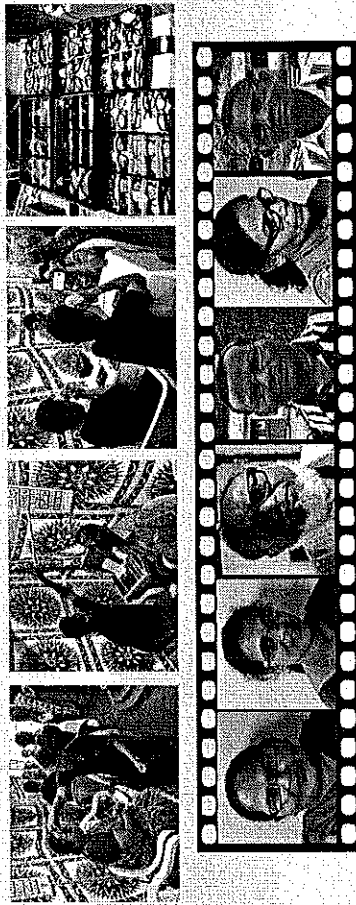


## India: Real-Time Telemedicine System

				
Reach Out	Screening	Test	Spectacles	Referral
Urban and rural population	App examines 7 anatomies, provides provisional diagnosis and screens out people who cannot undergo refraction	A 5 minute guided test which generates recommended power for your eyeglasses	We provide affordable and quality spectacles SV, BF, PALs	People who need higher level of care are screened and referred to Eye institutes & hospitals
5386 people processed in 160 days	5386 persons screened	1903 spectacle prescriptions	852 spectacles sold	2509 referrals & 43 eye surgeries performed with a 2000+ backlog



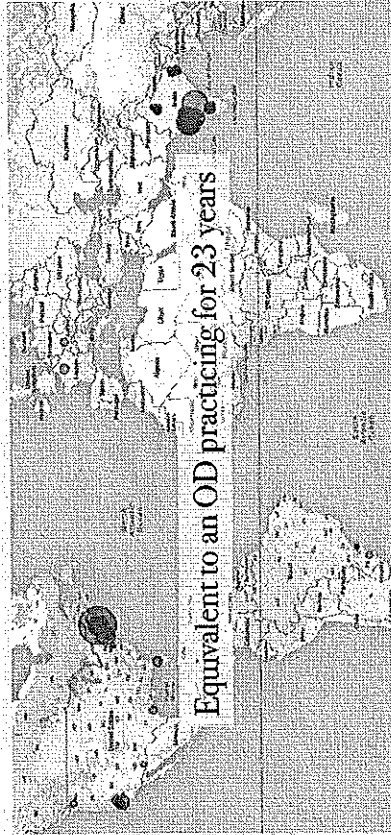
## Peri-Urban Stations / Mumbai Team



## Rural Station/ Tumkur Team



43,052 Refractions



## Regulatory Status

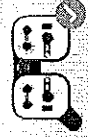
FDA Medical Devices  
Listed as Class 1 Exempt



The Nerra



The Netrometer



The Netropter

MDDS/HIPPA - HITECH  
Compliant Servers



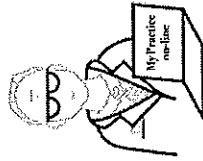
Future Milestones

1. Dec 2015 - ISO 13485 (QMS) Audit

2. Mar 2016 - CE Mark Approval

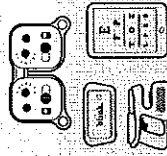
## EyeNetra for ECPs

1. Sign up



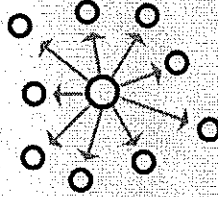
ECP signs up on-line and requests a kit

2. Receive Portable Clinic



Netra	Netrometer
Netropter	Tablet
EMR System	Scheduling System
Payment Solution	Visiometer Dashboard

3. Refract Anywhere



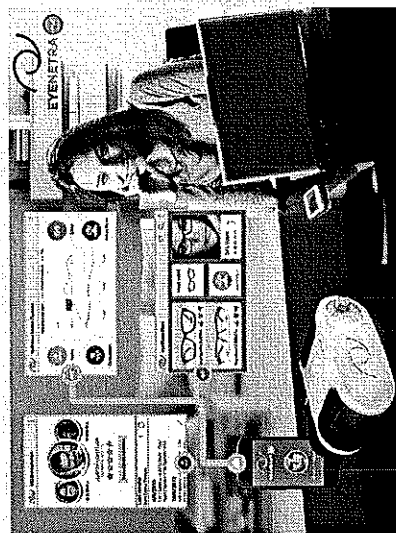
ECP hires / trains technicians to scale up practice

## EyeNetra Development

Key Programs

- Corneal Topography
- Retinal Imaging
- Tonometry
- EMR

Increasing access to better vision - everywhere



 **EYENETRA**

Increase Access  
Lower Costs  
Safe  
Friendly